V. APOLLO'S 510(K) SUMMARY K012029

V.1 Device Summary

Prepared:	November 1, 2001
Submitter's Name:	Apollo Corporation
Address, Phone, Fax:	P.O. Box 219 450 Main Street Somerset, WI 54025 Telephone: 715-247-5625 Fax: 715-247-3424
Contact Persons:	Adrian Sween Greg Soderberg
Device Trade/ Proprietary Name:	Remedy Model 2z12
Common/Usual Name:	UV Water Purifier
Classification Name:	Medical Ultraviolet Water Purifier 80KMG, Class II, Regulation 880.6710 General Hospital and Personal Use (per 21 CFR 880.6710)
Performance Standard:	No performance standards have been established under section 514 for indirect UV light water purifiers.
Substantial Equivalence:	This product is similar in design and function to the Aquanomics MP4SF manufactured by Cooper-Hewitt Electric Company which was subject to (PN) Pre-Market Notification #K813060. Other products substantially equivalent and subject to Pre-Market Notification (PN numbers listed below) are all manufactured by Cooper-Hewitt Electric Company bearing model numbers: HHU100 (PN #K813049), MP2SF (PN #K813048), MINI 60L (PN #K813047), HHU60 (PN 3 K813046), and SP36SF (PN K813045).

Description of Device: Apollo's Remedy® is a device designed to kill bacteria in water that is used to bathe patients in health care facilities. The unit contains quartz tubes which house and isolate germicidal ultraviolet lights from the water in a disinfecting chamber.

> The basic scientific concept using UV light to disinfect and purify both waste and drinking water has been studied and verified since the early 1950's and has been approved for such use by the FDA, EPA and the U.S. Public Health Service. Many of the independent sources have also proven the effectiveness and safety for disinfecting water using UV light in the 253.7 –nanometer wavelength.

Apollo's Remedy® uses a power source at or above 30,000 micro watts per second squared of Germicidal Ultraviolet light which is known to destroy bacteria and virus at the 253.7 –nanometer wavelength.

Once a patient is in the tub and the bath is filled, the water is continuously re-circulated through Apollo's Remedy® UV disinfecting device. This re-circulating provides a cumulative exposure to the UV source. The Apollo Remedy® is intended for use with Apollo bathing systems which utilize the existing whirlpool motor to re-circulate the water.

The Remedy® has no moving parts and is constructed of PVC piping, and the Remedy® is safe for users and the environment since no UV light is transmitted outside the disinfecting chamber.

Sensors are provided in the device to signal that the ultraviolet lights are on.

Intended Use: Apollo's Remedy® is intended for use only with Apollo whirlpool bathing systems in health care facilities where patients are bathed.

Apollo's Remedy® is intended for use in killing bacteria bio-load in bath water. The Apollo Remedy® consists of a disinfecting chamber housing two ultraviolet bulbs at power and wattage levels known to destroy various microorganisms at specific exposure

times. Once the patient is situated in a full tub of water, the water is continuously pumped and re-circulated through the Remedy® during the course of the bath, killing bacteria in the water as the bath progresses.

To date, only chemical disinfectants such as chlorine and Betadine have been available and used to protect bathers against bacteria present in the bath. There has been no device available which reduces bacteria levels in the bath water during bathing without potentially irritating chemicals. Apollo's Remedy® represents a significant benefit.

The substantial equivalent, AquaNomics MP4SF is intended to kill bacteria in water for drinking. Apollo's Remedy® is not intended to sterilize water for drinking. The bath water is not intended for re-use or consumption. The tub is drained at the conclusion of each bath and decontaminated through approved cleansing and disinfecting procedures prior to the next patients bath. In the unlikely event that an individual accidentally ingests the bath water, the bath water treated with Apollo's Remedy® should be less harmful due to the reduction of potentially harmful bacteria.

The intended use of the predicate device and Apollo devices is the same (killing bacteria in water) and the technology and procedure is the same and has been proven safe. However, the Apollo device is not intended to sterilize the bath water and any resulting reduction in bacteria in the bath water should be considered desirable.

The Remedy® is registered with the Environmental Protection Agency under EPA Est.#39712 OR-001, as it is a wastewater treatment technology.

Technological Characteristics: The construction of Apollo's Remedy® is PVC; AquaNomics is stainless steel. Both are compatible to ultraviolet light. Apollo's Remedy® houses the ultraviolet bulbs in sealed quartz tubes. The AquaNomics ultraviolet bulbs are contained in quartz sleeves. Both designs isolate the water chamber from the light bulb. The AquaNomics model is

designed to run continuously if water continues to flow, while Apollo's Remedy® will run intermittently only when the re-circulating whirlpool pump is running.

There are very few technical differences between the Apollo Remedy® and the AquaNomics MP4SF that Apollo claims is a substantially equivalent device. Both use the same ultraviolet technology and concept to attain similar results. The only major differences are the materials used in construction of the devices and the size of the units themselves. A comparison of the technical features of the two devices is included in Section IV. The predicate device is intended to kill bacteria in water to make the water pure for drinking purposes, and the Remedy® is intended to reduce bacteria counts in water to decrease the chance for bacterial infection and the spread of disease.

Assessment of Performance: Non-Clinical testing was completed on the Remedy® system taking water samples from bacterial contaminated water, with samples taken at specific minute intervals. The results showed a dramatic reduction in the bioload population, proving that the Remedy®was attaining expected results. A full report of the non-clinical Beta study conducted is included in the pre-market notification for review by the evaluator.

In-Vitro testing was conducted by an independent government recognized laboratory. The results of the tests reported "A kill factor on Pseudomonas aerruginosa was 99.9% at the end of the 15 miniute cycle indicating that nearly all the bacteria was destroyed as it passed through Remedy's® chambers. The kill factor on total coliform (E. coli) was 100% at the end of the 15 minute cycle indicating that all the bacteria was destroyed as it passed through Remedy's® chambers."

Ultraviolet light in the germicidal wavelength of 253.7 nm has been studied, used and accepted as a method to disinfect both potable and wastewater with no chemical residuals. The main criteria for disinfecting water with UV light are: flow rate, light intensity, distance from the source of light, and equipment maintenance. The data submitted,

referenced and relied upon in this submission proves that Apollo's Remedy® is substantially equivalent to the predicate devices approved by the FDA for marketing.

Both devices use the same power source and Germicidal Ultraviolet light, at or above 30,000 uW/second squared, which is known in all testing of such devices to destroy bacteria and virus at the 253 nanometer wavelength.

The effectiveness of ultraviolet light to kill microorganisms has been well established in numerous studies since the early 1900's. To set a standard of effectiveness, in 1966, the Department of Health, Education and Welfare, Public Health Service, established criteria for the acceptability of an ultraviolet disinfection unit guideline. This states that a minimum dosage of 16,000-microwatt seconds per squared centimeter for bacteria reduction is required. The FDA has accepted these standard requirements as regulation as stated in 21 CFR 179.39 (4/1/1993 edition).

Summary of Performance Data:

It is clear with the results of both non-clinical and In-Vitro testing that the Remedy® did and does exactly what Apollo Corporation is claiming (reduction of the bacteria bioload in bathwater), and is clearly equivalent to similar products that have previously been granted clearance for marketing from the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 31 2001

Ms. Adrian Sween
President
Apollo Corporation
450 Main Street
Somerset, Wisconsin 54025

Re: K012029
Trade/Device Name: Remedy Model 2Z12
Regulation Number: 880.6710
Regulation Name: Ultraviolet Water Purifier
Regulatory Class: II
Product Code: KMG
Dated: November 1, 2001
Received: November 5, 2001

Dear Ms. Sween:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III.2 Statement of Intended Use

Applicant: Apollo Corporation

510(k) Number: K012029

Device Name: Remedy Model 2Z12

Indications For Use:

Apollo's Remedy® is intended for use as an optional accessory with Apollo whirlpool bathing systems in which patients in healthcare facilities are bathed. This device is not intended to be sold as a separate, stand-alone device. The Remedy UV Water Purifier 2Z12 is a device that is intended for use only as an accessory on Apollo whirlpool bathing systems.

The Apollo Remedy® is designed to reduce bacteria levels in bath water during the bathing cycle.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012029